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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/336,392	06/18/1999	TERRENCE R. GREEN	25658-0002	7579

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EXAMINER

CHOI, FRANK I

ART UNIT	PAPER NUMBER
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1616

DATE MAILED: 01/16/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/336,392	Applicant(s) GREEN ET AL.	
	Examiner Frank I Choi	Art Unit 1616	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on 24 October 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 61,62,64-76 and 99-112 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 61,62,64-76 and 99-112 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 13) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.
a) ☐ The translation of the foreign language provisional application has been received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 10/24/2003 has been entered.

Specification

The lengthy specification has not been checked to the extent necessary to determine the presence of all possible minor errors. Applicant's cooperation is requested in correcting any errors of which applicant may become aware in the specification.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 61,62,64-76 and 99-112 rejected under 35 U.S.C. 112, first paragraph, as based on a disclosure which is not enabling. Method of incorporating enzymes into thermoplastic or thermosetting polymers and formulation in which mere wetting of device activates oxidase critical or essential to the practice of the invention, but not included in the claim(s) is not enabled by the disclosure. See *In re Mayhew*, 527 F.2d 1229, 188 USPQ 356 (CCPA 1976). Applicant's specification specifically states that room temperature vulcanization elastomers must be used in fabricating the device from hydrophobic polymers since enzymes will denature (Pgs. 31, 32). The claims require the use of thermoplastic or thermosetting polymers (See Claim 61). However, the claims also can include as proton donor or oxidizing agent an oxidase. There does

not appear to be any disclosure which shows how the oxidase can be incorporated in view of the prohibition against their use as indicated above. Applicant's specification indicates that with respect to glucose oxidase, the fluids must contain glucose and that even exposure to water does not release the oxidant (Pgs. 39,40) (Examiner notes that the same applies to other oxidases which require the presence of a substrate for activation). There does not appear to be a disclosure which shows how said oxidases can be activated by simply wetting the device absent presence of the appropriate substrate in view of the above.

Claims 61,62,64-76 and 99-112 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for the specific oxidant with the appropriate oxidizing agent, reducing agent and proton donating agent as disclosed in the Specification, and the disclosed processes of fabricating the devices does not reasonably provide enablement for oxidants, oxidizing agents and reducing agents or proton donating agents, where the disclosure is silent as to the appropriate combination of said agents or devices made by other process. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims.

The nature of the invention:

The invention is directed to the claimed anti-infective medical device made from a matrix of thermosetting or thermoplastic polymers in which the matrix contains as solid particles an oxidant-generating formulation comprising oxidizing agent and reducing agent that when wetted generates the oxidant, which can further contain a proton donor agent.

The state of the prior art and the predictability or lack thereof in the art:

The prior art of record does not appear to set forth oxidant-generating formulations different from that set forth in the specification. Further, Applicant's specification set forth what appears to be critical fabrication processes as set forth in the 112 first paragraph rejection above and 112 second paragraph rejection below. As such predictability in the art appears to be low with respect to the appropriate combinations of oxidants, oxidizing agents, reducing agents and/or proton-donors and fabrication processes other than which is set forth in the disclosure.

The amount of direction or guidance present and the presence or absence of working examples:

The amount of direction or guidance and working examples appears to be largely limited to iodine generating formulations and the appropriate oxidizing agents, reducing agents and proton donors for iodine generating formulations. There is some discussion of possible other oxidants, namely hydrogen peroxide, nitric oxide, hydroxy radical, hypohalites, haloamines, thiocyanogen and hypothiocyanite and the appropriate generating agents for the same. However, it is clear from the disclosure on pgs. 44-46, that not all the oxidant-generating formulations include or even mention the presence of both oxidizing agents and reducing agents, or proton donors in the formulation. Examiner acknowledges that the contacting fluids may contain one or more of the appropriate compounds necessary for the production of the oxidant, however, the claims require the presence of both an oxidizing agent and reducing agent and in some dependent claims a proton donating agent in the formulation itself. With respect to fabrication of the devices, the specification sets forth what appears to be critical fabrication processes as set forth in the 112 first paragraph rejection above and 112 second paragraph rejection below.

The breadth of the claims and the quantity of experimentation needed:

The claims are broad in that they claim any oxidant, oxidizing agent, reducing agent and proton donor and do not set forth the process by which the device is fabricated. It appears, in light of the above, that one of ordinary skill in the art would be required to do undue experimentation, i.e. to determine the appropriate oxidizing agent, reducing agent and proton donor for the specific oxidant, depending on type of polymer used for the matrix, and what other fabrication process would be suitable to form the claimed invention depending on the components of the claimed invention, other than what is set forth in the specification, in order to make and/or use the invention commensurate in scope with the claims.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 61,62,64-76 and 99-112 are rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential steps, such omission amounting to a gap between the steps. See MPEP § 2172.01. The omitted steps are: (1) mixing finely ground particles of the oxidant producing compound in to the polymer prior to its curing and/or fabrication, as a coating, or as a device, of specific dimensions and configuration (Pg. 26); (2) for hydrophobic polymers, fabrication of the inventive device requires that the oxidant-generating formulation first is ground to a fine powder of 200 microns or less, which dry formulation is then mechanically mixed at room temperature (20 to 25 degrees Celsius) in to a hydrophobic elastomer; (3) for formulations encapsulating enzymes, room temperature vulcanization elastomers must be used (Pg. 31); (4) for hydrophilic polymers, the oxidant formulations must first be premixed at low temperatures near the freezing point of water; (5) for oxidases, the required substrate must be present (pgs. 39,40); (6) critical fabrication steps of the hydrogel device include prechilling the

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gel-forming solution to less than 4 degrees celcius but not below freezing temperatures, adding and mixing in an oxidant generating formulation in the gel solution, casing the mixture into a mold and rapidly freezing and lyophilizing the mixture, alternatively instead of a mold that product can be formed into sheets (Pgs. 40,41).

Claims 69, 105 recites the limitation "alkali iodate salts". There is insufficient antecedent basis for this limitation in the claim. Examiner suggests that "anhydrous" be added to the limitation.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 61, 62, 64-66, 70, 99-102, 106,112 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Trescony et al. (US Pat. 5,994,444).

Trescony et al. expressly discloses a medical device comprising a polymeric material selected from polylactic acid, polyglycolic acid and copolymers thereof, having inorganic nitrite dispersed therein which in the presence of biological fluids yields an acid and reducing agent which generated nitric oxide, where the devices includes a stent or catheter or lead falling within

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the scope of applicant's claims, where when the reducing agent is potassium iodide, iodine is also produced (See Column 5, lines 23-68, Column 6, lines 1-15, claims 1-27).

Alternatively, at the very least the claimed invention is rendered obvious within the meaning of 35 USC 103, because the prior art discloses products and uses that contain the same exact ingredients/components as that of the claimed invention. See *In re Fitzgerald*, 205 USPQ 594 (CCPA 1980). See also *In re May*, 197 USPQ 601, 607 (CCPA 1978).

Conclusion

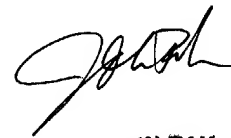
A facsimile center has been established in Technology Center 1600. The hours of operation are Monday through Friday, 8:45 AM to 4:45 PM. The telecopier number for accessing the facsimile machine is (703) 872-9306.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Frank Choi whose telephone number is (703) 308-0067. Examiner maintains a flexible schedule. However, Examiner may generally be reached Monday-Friday, 8:00 am – 5:30 pm (EST), except the first Friday of the each biweek which is Examiner's normally scheduled day off.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's Supervisor, Mr. Thurman Page, can be reached on (703) 308-2927. Additionally, Technology Center 1600's Receptionist and Customer Service can be reached at (703) 308-1235 and (703) 308-0198, respectively.

FIC

January 12, 2004



**JOHN PAK
PRIMARY EXAMINER
GROUP 1600**